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In the Supreme Court of the United States

OCTOBER TERM, 1948

No. 134

RESEARCH LABORATORIES, INC., PETITIONER

v.

UNITED STATES OF AMERICA

BRIEF FOR THE UNITED STATES IN OPPOSITION

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE NINTH CIRCUIT

OPINION BELOW

The opinion of the circuit court of appeals (R. 1102-1134) is reported in 167 F. 2d 410. The district court did not render an opinion.

JURISDICTION

The judgment of the circuit court of appeals was entered April 2, 1948 (R. 1135). The petition for a writ of certiorari was filed July 1, 1948. The jurisdiction of the court is invoked under Section 240(a) of the Judicial Code, as amended by the Act of February 13, 1925.

QUESTIONS PRESENTED

1. Whether, in a libel for condemnation action instituted against a drug under the Federal Food, Drug, and Cosmetic Act, evidence introduced by the Government with respect to actual use, clinical observations, and knowledge of value of constituent ingredients constitutes factual data which may be submitted to the jury to determine whether the therapeutic claims made in the labeling are false and misleading?

2. Whether petitioner's drug was shown to be misbranded under Section 502(a) of the Federal Food, Drug, and Cosmetic Act because its labeling failed to meet the requirement of Section 201(n) of the statute?

STATUTE INVOLVED

The Federal Food, Drug, and Cosmetic Act of June 25, 1938, c. 675, 52 Stat. 1040, 21 U.S.C. 301 *et seq.*, provides in part:

> SEC. 201. For the purposes of this Act—
>
> * * * * *
>
> (g) The term "drug" means . . . (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals . . .
>
> * * * * *
>
> (m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.
>
> (n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or

any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

* * * * *

SEC. 304. (a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found . . .

(b) The article shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury . . .

* * * * *

SEC. 502. A drug or device shall be deemed to be misbranded—(a) If its labeling is false or misleading in any particular.

* * * * *

STATEMENT

Pursuant to Section 304(a) of the Federal Food, Drug, and Cosmetic Act, the United States filed four libels of information for the seizure and con-

demnation of various lots of a drug known as Nue-Ovo (R. 2, 56, 78, 92), which had been shipped in interstate commerce by petitioner. On stipulation of the parties, an order was entered consolidating all four causes for trial in the District Court of the United States for the Western District of Washington (R. 16-18).

Each of the libels charges that the drug, Nue-Ovo, is misbranded under Section 502(a) in that the statements in its labeling are false and misleading since they represent, suggest, and create the impression in the mind of the reader that the product is effective in the treatment of arthritis, rheumatism, neuritis, sciatica, and lumbago, whereas it is not effective in the treatment of those conditions.

As a result of pre-trial conferences, certain facts were agreed upon and incorporated into a pre-trial order (R. 18-29) which stated the issues to be as follows:

(1) Whether the product is ineffective in the treatment of arthritis, rheumatism, neuritis, sciatica, or lumbago (R. 23).

(2) Whether the labeling of the product suggests to the user that Nue-Ovo is effective in the treatment of arthritis, rheumatism, neuritis, sciatica, or lumbago (R. 23).

(3) Whether the product is misbranded by reason of the labeling (R. 23).

Evidence adduced by the Government demonstrated these facts:

(1) The labeling of the product suggests to the user that the product is effective in the treatment of

arthritis, rheumatism, neuritis, sciatica, and lumbago. This is admitted by petitioner (R. 1068, 1105).

(2) Most of the ingredients in Nue-Ovo have long been abandoned, or were never accepted, in medical practice because of their complete lack of therapeutic value (R. 190-264). It is a basic principle in pharmacology, a science that deals with the study of how drugs act (R. 191), that when two or more drugs are combined, the combination has no properties over and above the properties of the individual (R. 203). Those ingredients which do have a place in present-day medicine are present in Nue-Ovo in such minute quantities as to be of no value in the treatment of the disease conditions for which it is recommended (R. 204-228, 582).

(3) Clinical testing of Nue-Ovo upon patients under controlled conditions by experts in the treatment of arthritic and related conditions reveals that the product is wholly ineffective in the treatment of arthritis, rheumatism, neuritis, sciatica, and lumbago (R. 265-277, 319-359, 397-405). Almost parallel results were obtained when one group of patients was treated with a placebo (R. 355).[1] In one study, the group on Nue-Ovo showed no change, while the group on the placebo showed some improvement (R. 403).

Apart from these clinical observations, a specialist in therapeutics and other qualified physicians testified that from their knowledge of the ingredients of Nue-Ovo, and of the diseases for

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[1] An inert substance made to look and taste like Nue-Ovo (R. 218, 219).

which it is offered, the product could not be effective in the treatment of any of those diseases (R. 223-231, 485-488, 558-563, 578-582).

(4) False statements and half truths had been utilized in the labeling and marketing of the product. The factual evidence to this effect presented by the Government demonstrated that petitioner had used false testimonials (R. 418-473, 662-674), deceptive methods in the use of the mails (R. 607-620, 898-908), and significant and deceptive omissions in the labeling of the product in respect to the analysis of its ingredients (R. 833-847).

Evidence adduced by petitioner was largely of the lay user type. Of 36 witnesses and one deposition, 30 were lay users. One physician, Dr. G. M. Taylor, testified that he had conducted clinical studies not with Nue-Ovo, the product under seizure, but with Sal-Trag,[2] another product manufactured by petitioner (R. 969-984). He concluded that Sal-Trag was effective in the treatment of arthritis, rheumatism, lumbago, and neuritis, but not for sciatica (R. 973-974). He could not account for the curative effects of Sal-Trag (R. 973). When pressed for an answer, he stated that the herb ingredients of Sal-Trag are not used in present-day medicine (R. 981-982).

Another physician called by the petitioner, Dr. Carl E. Lund, uses Sal-Trag in his practice in the

[2] The identity of Nue-Ovo with Sal-Trag became an issue in the case, since it was admitted that Sal-Trag contained two ingredients not present in Nue-Ovo, ephedrine and methenamine (R. 792, 803). The court charged the jury to consider evidence with respect to Sal-Trag only if it found that Sal-Trag and Nue-Ovo are one and the same except with respect to the difference they possess by reason of the higher degree of evaporation in Sal-Trag (R. 1065).

treatment of arthritis, rheumatism, neuritis, sciatica, and lumbago (R. 994). He could not explain the curative effects he stated had been obtained (R. 1012). He was not aware that the medical profession has abandoned use of the herb constituents in Nue-Ovo (R. 1016).

Still another physician who testified on behalf of petitioner, Dr. Ira A. Manville, conducted clinical investigations using both Nue-Ovo and Sal-Trag (R. 802). During part of the time when he conducted these studies, he was on the payroll of petitioner (R. 833). Some of the laboratory examinations connected with the studies were made on the premises of petitioner (R. 834). In computing the results of his studies, he admitted that he had thrown out the averages of one patient because they were extraordinarily high and would have thrown his ultimate averages out of line (R. 851).[3]

Petitioner's doctors admitted they would not use Sal-Trag or Nue-Ovo in the treatment of alcoholic neuritis (R. 753); pain in the back (lumbago) due to overwork (R. 753); sciatica (R. 974); acute sciatica (R. 754); acute traumatic arthritis (R. 755); syphilitic, gonorrheal, or other infectious arthritis (R. 756, 862); and neuritis resulting from a mechanical impairment (R. 980).

As a rebuttal witness, and without changing its position that clinical observations with respect to

[3] An accepted factor in arthritis, rheumatism, neuritis, sciatica, and lumbago is that they are characterized by intermittent periods when the pain leaves the patient entirely, and by periods when the pain is heightened (R. 220-221, 347-348). Dr. Manville admitted that the high improvement which he claimed he noted in his clinical studies might in many cases be attributable to a normal period of lessened pain following administration of the drug (R. 873; cf. R. 220-221).

Sal-Trag were not admissible, the Government called a physician, Dr. Harry H. Dutton, who testified that he had conducted clinical studies with Sal-Trag at the request of petitioner and had detected no improvement in any patient (R. 1031-1034).

At the close of the evidence, petitioner moved for a directed verdict (R. 1045) upon the ground that the evidence showed only a conflict of expert opinion as to the effectiveness of the drug (R. 1045-1046). This motion was denied (R. 1050). The jury found in each case that the product was misbranded as charged (R. 33, 69, 84, 98). On appeal, the circuit court of appeals affirmed the judgments (R. 1134).

ARGUMENT

1. Petitioner contends that it was improper to submit the case to the jury because there was an honest difference of medical opinion concerning the effectiveness of the product. In support of this contention, petitioner cites *American School of Magnetic Healing* v. *McAnnulty*, 187 U. S. 94, *United States* v. *Johnson*, 221 U. S. 488, and *Seven Cases of Eckman's Alterative* v. *United States*, 239 U. S. 510.

Petitioner urges that it is the rule of the *McAnnulty* case that if there is an honest difference of medical opinion the court must direct a verdict for the claimant. It is clear, however, that the *McAnnulty* rule is limited to those cases in which the question of the effectiveness of the treatment is a matter of opinion and is not resolved by demonstrable, definitive proof.

In seeking to ascertain whether Nue-Ovo has any efficacy in the treatment of the disease conditions

for which it is offered, the Government arranged to have a series of clinical studies conducted by eminently qualified physicians. Studies were conducted by Dr. John H. Wheeler, a practicing physician in Kansas City, Missouri, at the Out Patient Department of the University of Kansas (R. 265-272). Of six patients suffering from arthritis who used the medicine for a period of six weeks during 1944, three patients experienced no improvement, two were of the opinion that they were no worse, and one patient felt that he was definitely improved but complained of some new pain involving both knees (R. 269). In 1940, 23 patients suffering from arthritis were requested to use the preparation. Of these who used it for various intervals, two for two weeks and the rest for periods varying from two months to nine months, 18 experienced no improvement, the symptoms of three improved slightly, and two were of the opinion that they felt better. (R. 270, 271.)

Studies were carried on under carefully controlled conditions in the clinic of the University of California by Dr. Frances Baker, Director of the Department of Physical Medicine at the University, who had specialized in the study of arthritis (R. 319-357). The first test involved 20 patients. Fourteen were treated with Nue-Ovo and eight with a placebo (see *supra*, p. 5) for a period varying from 4 to 18 weeks. (R. 354.) One patient felt improved, one felt worse, two had such severe pain that a change in treatment was required, and the rest were unchanged. Almost a parallel result was obtained with the placebo (R. 355). Another test involved six patients over a period of two months. Five patients stated that they felt no better (R.

351, 352). Tests were also conducted by Dr. W. D. Edwards, a physician at a medical institution near Los Angeles. The patients suffering from arthritis disclosed no improvement, though apparent improvement was claimed by some of the group that were treated with the placebo (R. 397-404).

In addition to this testimony regarding actual clinical proof as to the inefficacy of Nue-Ovo, the Government presented the scientific pharmacological evidence referred to at page 5, *supra,* to establish that most of the ingredients in Nue-Ovo have no therapeutic value, (2) that a combination of such ingredients does not impart to the product any therapeutic properties which the individual ingredients do not have, and (3) that such ingredients of Nue-Ovo as are used in modern medicine are present in such minute quantity as to add no therapeutic value to it.

Physicians who had not made clinical studies as to the efficacy of Nue-Ovo, but who were shown to be qualified to express their opinion thereof without such studies, testified that the product would not be effective in the treatment of any of the diseases for which it was offered (R. 223-231, 486-488, 558-563, 578-582).

The Government's evidence, therefore, was by no means limited to the proffer of opinions as to the therapeutic value of the drug. It included factual data of the actual progressive results of elaborate and comprehensive tests of the drug made by eminently qualified persons on human beings suffering with the disease for which the drug was represented as a remedy. It also included evidence which established as a scientific fact that most of the ingredients in the product have no therapeutic value,

together with the consensus of medical opinion on this point (R. 1117).

Petitioner's contentions are premised upon the assumption that, as a matter of constitutional law, Congress may not permit a claim of effectiveness on behalf of a drug product to be found false or misleading by a jury when a difference of medical opinion exists. In the *McAnnulty* case, involving the issuance of a fraud order by the Postmaster General, this Court held that the claims of effectiveness made on behalf of the school could not be condemned as false, since there existed a difference of medical opinion and consequently there was no standard of fact which could be utilized to ascertain the truth or falsity of the representations. It is clear, however, that tremendous strides in science and medicine have been made since the *McAnnulty* decision, and that numerous questions with respect to which only opinions formerly existed have now been resolved by newly evolved scientific principles based on factual data. In any event, it is apparent that Congress so worded Section 502(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352), with the *McAnnulty* decision in mind, as to permit claims of effectiveness made on behalf of a drug to be found false or misleading where that issue can be demonstrated to a jury as a fact.[4] No better evidence as to the safety or effectiveness of the drug can be adduced than the actual results of the use of the prod-

[4] This is made clear in that portion of the legislative history quoted in the Appendix *infra*, pp. 18-20). Historical development in the judicial attitude toward products offered to the public for the treatment of disease is thoroughly analyzed in *United States* v. *7 Jugs* * * * *Dr. Salsbury's Rakos*, 53 F. Supp. 746 (D. Minn.).

uct by a patient under the direction of a qualified expert. As the judge who presided at the trial lucidly said, in denying petitioner's motion for a judgment notwithstanding the verdict (R. 1094):

> * * * it is not an expression of opinion when the Government experts say they conducted clinical tests in which unknown to the patients, they gave some of them, whether there were large numbers or small numbers, in the aggregate they were a very considerable number of persons in the various clinical tests, the remedy Nue-Ovo and others they gave a placebo, each of them thinking they were taking a remedy that was an effective treatment for arthritis, and each of these patients unquestionably afflicted with arthritis in its advanced stages. And in all instances the results of pain were almost identical, whether they took the colored water or whatever it was, or some bitters, or whether they took this remedy.
>
> Now that's a matter of fact. That isn't a matter of opinion, if the jury saw fit to believing.

Certainly it cannot be stated that the evidence of results obtained by competent scientific investigation cannot be used to ascertain the truth or falsity of therapeutic claims. This proposition was recognized by this Court in *Seven Cases of Eckman's Alterative* v. *United States,* 239 U. S. 510, 518, where it was pointed out, with respect to the Food and Drug Acts of 1906, that although Congress had deliberately excluded the field where there were honest differences of opinion, "Congress recognized that there was a wide field in which assertions as to curative effect are in no sense honest expressions of opinion but constitute absolute falsehoods * * *." In the present case, the sig-

nificant fact is that the Government introduced evidence designed to establish as a fact, upon the basis of actual use, clinical observations, and knowledge of the constituent ingredients of Nue-Ovo, that the product is not effective in the treatment of arthritis, rheumatism, neuritis, sciatica, and lumbago. Further, the consensus of medical opinion (as distinguished from the casual opinion of one or more doctors) as to the therapeutic value of a drug or medicinal ingredient is necessarily based upon the history of its actual use over such a period as to establish its characteristics as an accepted fact.

The *McAnnulty* case did not hold that, in any case where a difference of medical opinion is shown, the trial court must direct a verdict against the Government irrespective of other evidence in the case. As pointed out above, it was recognized in *Seven Cases of Eckman's Alterative* v. *United States, supra,* that there is a category of assertions as to curative or therapeutic effect which falls outside the realm of opinion and can be demonstrated by factual evidence as constituting absolute falsehoods. Where there is a standard of demonstrable fact by which a claim of effectiveness can be measured, the rationale of the *McAnnulty* opinion, that claims of effectiveness as to which there is a difference of medical opinion cannot be condemned as false since there is no standard by which to measure the falsity or truth of the claims, is not applicable. This was pointed out specifically in *United States* v. *7 Jugs * * * Dr. Salsbury's Rakos,* 53 Fed. Supp. 746 (D. Minn.), where the court declared (pp. 758, 759):

> If the evidence is such that it appears that the question of effectiveness has not tran-

> scended the realm of opinion into the realm of demonstrable fact, the court must hold as a matter of law that assertions of effectiveness are not false and refuse to submit the question to the jury. * * * But where the evidence indicates that there is a standard of demonstrable truth and fact by which the jury can measure the claims of effectiveness, the court should then submit the question to the jury under appropriate instructions. * * *
>
> * * * * * *
>
> * * * Certainly where factual proof is present which indicates the worthlessness of the remedies in question, mere injection of an alleged difference of opinion on the part of persons whom the jury might find were either ignorant or charlatans, could not operate to prevent the jury from deciding the question of effectiveness. Under the evidence in this case, the jury was entirely warranted in finding that the contrary expressions of opinion by the witnesses appearing for claimant were in direct oppositions to established scientific fact.

It is plain, therefore, that petitioner has failed to take into account that, as pointed out by this Court in the *Seven Cases of Eckman's Alterative* case, the rule of the *McAnnulty* case does not apply in a field in which statements as to curative properties are downright falsehoods and in no case expressions of judgment. In any case which involves the therapeutic value of a drug, the question will ordinarily arise whether its lack of effectiveness can be demonstrated as a fact or whether there exists merely a difference of opinion. The circuit court of appeals clearly recognized that this problem exists, in holding that the evidence submitted by the Government fell within the field of demon-

strable fact upon the basis of which it could be determined by the arbiter of the facts that the therapeutic claims made on behalf of petitioner's product were false and misleading.

2. Aside from the question as to whether the Government demonstrated by factual evidence that the therapeutic claims made on behalf of petitioner's product were false and misleading, the verdict of the jury is supported by undisputed evidence of misbranding under Section 201(n) of the Act, *supra,* pp. 2-3.

If, as petitioner asserts, an honest and bona fide difference of opinion exists among practitioners and experts as to whether its product is effective in the treatment of the diseases named in the labeling, then it is clear that labeling which represents the article as effective must disclose that a difference of opinion exists with respect thereto.[5] The legislative history of the Act discloses that, in the consideration of Section 201(n), Congress had particularly in mind those representations as to therapeutic effect regarding the truth of which expert opinions might differ. Contrary to the assertion in the petition (p. 9), it is abundantly clear that Congress specifically intended the section to cover such situations. As shown by H. Rep. 2139, 75th Congress, 3d Session, *infra,* pp. 18-20, accompanying S. 5 which later became the Federal Food, Drug, and Cosmetic Act of June 25, 1938, Congress was aware of the rule of the *McAnnulty* case, but at the same time realized that in the marketing of drugs it

[5] The printed and graphic matter representing the labeling in this case is found in the record at pages 7, 8, 8A, 60, 63, 64 and 65. No semblance of compliance with the requirements of Section 201(n) is demonstrated.

would be most undesirable to permit misleading claims to be made simply because a few so-called experts could invariably be found to support them.

We must disagree with the statement contained in the footnote on page 9 of the petition to the effect that this case was not tried and decided on the issue of failure to reveal the existence of overwhelming opinion contrary to petitioner's claim for his product. The trial court, in charging the jury, quoted Section 201(n) (R. 1058), and then gave the following instruction (R. 1058-1059):

> It is therefore for you to determine, after a careful examination of the Government's exhibits entitled Exhibits 1, 2, 3 and 4, and all of the other evidence introduced in this case and all of the facts and circumstances disclosed during the course of the trial, whether there was a misbranding by reason of any representation that might mislead an ordinarily intelligent person, whether such statements be direct assertions of fact or the logical inferences to be drawn from the facts contained in the statement. Then you will also note from the law that I have quoted to you, that as a test to be applied to ascertain if the labeling is misleading, you will take into account not only the representations made or suggested by the words "design," "device," or any other combination thereof, or any combination thereof, but you will also take into consideration the failure to reveal facts, if any, that would be material in the light of representations made with respect to the consequences which would result from the use of the article when it is used in the manner indicated.

Clearly, the failure of the labeling to disclose the large body of opinion contrary to the therapeutic

claims made in such labeling constitutes a misbranding in that it is a failure under Section 201(n) to reveal facts material in the light of such claims. Consequently, the jury's verdict was justified irrespective of the issue of the effectiveness of the product.

CONCLUSION

The case was correctly decided below, and it presents no conflict of decisions and does not go beyond the doctrine of the *McAnnulty* and *Seven Cases of Eckman's Alterative* cases. We respectfully submit, therefore, that the petition for a writ of certiorari should be denied.

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JULY 1948.

APPENDIX

H. Rep. 2139, 75th Congress, 3d Session, accompanying S. 5, which later became the Federal Food, Drug, and Cosmetic Act of 1938, contains the following in respect to section 201(n) (p. 7):

Section 502 defines misbranded drugs and devices. In its first paragraph it makes an extremely important contribution to existing law in defining a drug as misbranded if its labeling is false or misleading in any particular. The present law contains this provision with respect to representations concerning the identity, strength, quality, and purity of the drugs, but therapeutic claims are amenable to action only if they are false and fraudulent. The persuasive effect of a false label on the consumer's mind is the same whether the representations were made in good faith or not. It has been demonstrated that effective protection of the public from falsely labeled nostrums is in many cases impossible under this language. This provision differs from that of the Senate bill (sec. 17 (a)), in that it omits the explanatory sentence:

> Any representation concerning the effect of a drug or a device shall be deemed to be false and misleading under this paragraph if such representation is not supported by persons who, by reason of scientific training and experience, are qualified as experts on the subject to which such representation relates.

It was felt that if a nostrum maker were able to obtain two or more persons who could qualify as experts and would testify in support of the label claims, the Government's case would be lost despite the fact that every competent expert in the country would unqualifiedly declare the claims to be false. The committee therefore substituted for this provision section 201(n).

This section is also offered as a solution to a difficult legal problem. It is a well-known principle of

law that a statute providing punishment for the commission of an offense must describe the offense with a reasonable degree of certainty. There are clear implications in cases arising under the old Food and Drugs Act and other laws that Congress may not, by a simple and unqualified prohibition against misleading representation, penalize the making of a representation of therapeutic effect regarding the truth of which expert opinion differs (Seven Cases *v.* United States, 239 U. S. 510; United States *v.* Johnson, 221 U. S. 488; American School of Magnetic Healing *v.* McAnnulty, 187 U. S. 94).

The reason for this limitation on the power of Congress is apparent. Whether the labeling of an article would be misleading and the product be thus misbranded would depend in a prosecution on whether the jury found it to be misleading.

If the Congress were to provide that a representation, about the correctness of which qualified opinion differed, would be misleading if the jury agreed with the experts holding one view but not misleading if the jury agreed with the experts holding the other view, it is apparent that the manufacturer would be unable to tell in advance whether his labeling violated the statute. There would therefore exist the kind of uncertainty which would invalidate the statute. But it is undesirable to permit misleading claims to be made simply because a few experts can be found on the occasion of a trial to support them.

One of the important applications of section 201(n) relates to this problem. If only a few experts regard a label statement of curative value as true but the great body of qualified experts in that particular field regard the statement as untrue, then there may be substantial ground for concluding that the curative claim is misleading unless it is qualified in such a way as to show the existence of conflicting opinion as to its truth. Certainly a

consumer seeking a remedy for a disease condition has the right to know, when it is a fact, that the representations of curative value have only a narrow and limited support; and if the labeling fails to reveal that fact, which is a material fact in the light of the representations made, then the labeling may be regarded as misleading. However, the misleading character of the label may be corrected by an appropriate qualifying statement revealing this material fact.

In such circumstances, therefore, the manufacturer can easily ascertain by consulting qualified experts in the field whether there is a material weight of opinion contrary to claims he desires to make, and there would exist no uncertainty of the kind that would invalidate the statute.

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